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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,818	01/13/2004	Stephen James Russell	07039-416002	2374

26191 7590 08/24/2005

FISH & RICHARDSON P.C.
PO BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER	
LIETO, LOUIS D	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 08/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/756,818	Applicant(s) RUSSELL ET AL.
	Examiner Louis D. Lieto	Art Unit 1632

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 05 August 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *05 August 2005*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: _____.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

Deborah Crouch

DEBORAH CROUCH
PRIMARY EXAMINER
GROUP 1600 1630

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Continuation of 11. does NOT place the application in condition for allowance because:
Claim Rejections - 35 USC § 112

The rejection of original or amended claims 19-26 under 35 U.S.C 112, first paragraph for lack of enablement is maintained for reasons of record stated in the office actions of 6/03/2005 and 12/01/2004. Applicant's arguments filed on 8/05/2005 have been fully considered but they are not persuasive.

Applicant argues that Examiner believes that gene therapy will not be enabled until it is clinically available in humans, and cites In re Brana in defense of their position. However, Brana can be distinguished from the instant application for several reasons. First the fact pattern is different; Brana is drawn to pharmaceutical compounds, while the instant invention is one of gene therapy. Second, the claims in Brana are drawn to a compound, while the claims of the instant application are drawn to a method of using nucleic acid sequences in gene therapy. Applicant is incorrect in their conclusion that the examiner believes that gene therapy will only be enabled when it is clinically available in humans. The issue of hand is whether applicant has disclosed sufficient information to enable the claimed method for use in cancer therapy. The requirement for full enablement is that the specification teaches how to practice the claimed invention to the full extent of the scope of the claims. As previously noted, applicant has only provided data from in vitro experiments. As previously stated, the disclosed in vitro experiments are insufficient to enable the claimed methods for the stated use of "cancer therapy." The only disclosed purpose for the claimed methods is for therapy (e.g. pg 2, line 12, "cancer therapy"; pg 3, lines 2 1-23, "leukocytes that elicit an anti- tumor effect" pg 8, line 24, "therapeutic (immunogenic) protein"). As evidenced by the references cited in the previous two office actions, there is a level of general unpredictability in the art of gene therapy, which requires a detailed disclosure that would allow one skilled in the art to predictably practice the claimed invention. Case law teaches (Ex parte Forman, 230 USPQ 546,547 (BPAI 1986)) that "the disclosure of a patent application must enable practice of the invention claimed without undue experimentation", wherein factors involved in the determination of undue experimentation were deemed to include "the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in that art, the predictability or unpredictability of the art and the breadth of the claims." The quantity and complexity of experimentation necessary to practice the claimed invention, as a method of cancer therapy requires that the skilled practitioner determine the combination of specific nucleic acid encoded polypeptide, vector, promoter, level of expression, target tissue, dosage, route of administration, and disease to be treated in order to obtain a therapeutic effect using gene therapy. "Case law requires that the disclosure of an application shall inform those skilled in the art how to use applicant's alleged discovery, not to find out how to use it for themselves." In re Gardner 166 USPQ 138 (CCPA) 1970.

The rejection of original or amended claims 19-26 under 35 U.S.C 112, second paragraph for being indefinite is maintained for reasons of record stated in the office actions of 6/03/2005 and 12/01/2004. Applicant's arguments filed on 8/05/2005 have been fully considered but they are not persuasive.

Applicant does not raise any new arguments in their response. The term altering in the context of claim one is equivalent to an open ended numerical range that encompasses any change in the amount of regulatory drug to which said cell is exposed. As such the term is indefinite.